



Montana Labs, LLC.

March 29, 2018

Montana Department of Health & Human Services
Sheila Hogan, Director
Darci Wiebe, Bureau Chief, Medical Marijuana
Kenneth Mordan, Office of Legal Affairs
P.O. Box 4210
Helena, MT 59604-4210

Ms. Hogan, Ms. Wiebe and Mr. Mordan,

After reviewing the law passed by the 2017 Legislature and the final rules, we believe we have grounds to formally request the Department enter into rulemaking. We formally request that the Montana Department of Health and Human Services enter into rulemaking for the purpose of both adoption of, and amendment to rules pertaining to the Medical Marijuana program. Based on the current rules non-compliance with existing law (SB 333 passed by the 2017 Legislature) we request a hearing and that the department enter into rulemaking within 60 days as per MCA 2-4-315.

As required, the following are a compilation of specific topics where the current proposed rules are in conflict with the statute. We offer the following list:

1. The purpose (MCA 50-46-301) of the legislation was to improve the regulatory system, lax rules do not accomplish this.
2. The second purpose of the legislation was to allow for *limited cultivation*, the proposed 50 square foot canopy is more than is allowed in recreational states and encourages the black market with overproduction.
3. The definition of employee (MCA 50-46-302(7) in this section of MCA is vague. Due to disagreements in the marketplace we have continued to request that the department clarify this ambiguity. The MCA gives the department broad rulemaking authority. The Department has refused to clarify this matter and are currently allowing a definition that is contrary to Montana Independent Contractor law. Again, creating a market inviting corruption.
4. Testing labs are defined in MCA 50-46-302 (26) as providing information regarding the chemical composition, the potency and the presence of molds and pesticides. There is a commonly used list of allowable amounts of pesticides used among legalized jurisdictions. The department has randomly removed over half of these from the list, therefore creating a process where the product could be heavily laced

- with pesticides and the consumer will not have any way of knowing this. However, the product will be labeled as tested to be pesticide free.
5. Although MCA 50-46-308 (2) clearly indicates that the rules of licensure apply to everyone with a financial interest, the ARM is not adequately addressing this. They have defined financial interest and indicated that everyone must comply. However, they do not require any financial disclosures from the applicant nor are they included in the application. The applicant simply can get money from anywhere and choose not to report this. This is inviting the illegal market to enter into our program as investors.
 6. MCA 50-46-311(2) requires the department to set by rule a number of items concerning labs. How staff will demonstrate proficiency in operation of the equipment; maintenance of and requires for equipment and bonding and insurance requirements. The current ARM does none of this.
 7. MCA 50-46-312 (1)(b) requires the department to consider suitability of premises. Other areas of both the MCA and ARM have requirements regarding premises access, inspection, etc. Although the ARM attempts to define premises, it is still very vague. Is it the entire lot encompassed by the address on the application? Is it only the kitchen or basement of a home? Is it the children's bedrooms of that same home? Does it include a shared parking lot or bathrooms in an office complex?
 8. The most egregious, and the problem presenting the most urgency, is that the ARM is not complying in any way with MCA 50-46-326 which requires the department to establish sampling protocol by rule. If you read the current ARM, it almost appears that the department thinks the grower will send the entire five pound test lot into the lab. It has absolutely no protocol for how a sample is supposed to be harvested from the lot. In MCA 50-46-329 the department is required to inspect every location every year. They are also required to take a test sample and have it tested. The ARM does not address how they will choose where to send the sample, how it will be handled in delivery, time-tables for turn-around, nor who is going to pay for this testing.
 9. This same section gives the department rulemaking authority for establishing penalties for failure to meet agriculture and public health requirements. The department was asked during their first round of rulemaking to address this and responded that they felt revoking a license until they comply and then returning that license was good enough. This makes no logical sense and we do not feel this is what the legislature intended. Selling illegal product from Oregon should not have

the same consequences as having a dirty bathroom during inspection. Both can be remedied quickly. Do we intend to give illegal operators their license back every time they "correct" what they were doing wrong?

a. We recognize that this particular section of MCA addresses health issues.

However, the entire SB 333 gave the department broad rulemaking authority to enforce the entire act.

10. In the currently adopted ARM, the department is insisting that all licenses must be Montana residents. New rule IV. This was discussed at length during the legislative debate and was determined that they were NOT going to require testing labs to be Montana residents. The Department is creating a rule where no authority in law allows.
11. In the currently adopted ARM, New Rule V, the department suggests that they have agreed with comments to allow for on premise consumption and changed the rules accordingly. Although they did so in one section, they did not complete the task and the rule still requires signage (5)(b) stating no on site consumption. This should be clarified one way or the other.
12. New Rule X (7) addresses foreign matter in the test sample. The department was asked to clarify if the percentage allowed was a percentage of weight or volume. The final rules did not answer this. They are two different calculations.
13. New rule X now requires random testing for heavy metals. It does not define how this randomness will be determined. Will each lab need to have the necessary equipment to do this testing? Who will pay for the testing? The state or the grower?
14. We believe we have standing to ask that the department review their decision to eliminate allowable amounts for so many different pesticides. The intent of the legislature was to provide a safe product. To simply determine that more than half of the pesticides normally regulated are not regulated in Montana is deceptive. The test results will then say that the product tested "pesticide free" when it actually may contain very high amounts of a huge number of different pesticides. Although the department was lead to believe that this lowers the cost of testing, it does not. The lab still needs to invest the same amount in the capitol purchases for equipment and the "usable" items referred to, are generally purchased in industry standard bundles that would include those pesticide tests.
15. To further insure public safety, we request the department also review New Rule X. The department chose to not adopt the proposed rule to test for water activity rate

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